UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

MARY BAYES and PHILIP BAYES,

Plaintiffs,

v.

BIOMET, INC., BIOMET ORTHOPEDICS, LLC, BIOMET U.S. RECONSTRUCTION, LLC, BIOMET MANUFACTURING, LLC f/k/a BIOMET MANUFACTURING CORP.,

Defendants.

Case No. 4:13-cv-00800-SRC

MEMORANDUM IN SUPPORT OF PLAINTIFFS' OMNIBUS MOTION *IN LIMINE*

Plaintiffs, Mary Bayes and Philip Bayes, move *in limine* to preclude Defendants, Biomet, Inc., Biomet Orthopedics, LLC, Biomet U.S. Reconstruction, LLC, Biomet Manufacturing, LLC F/K/A Biomet Manufacturing Corp. (collectively "Biomet") (together, "Defendants"), from presenting the eleven categories of evidence described below.

This is a products liability case where Plaintiffs have alleged strict liability and negligent design defect claims, as well as claims for loss of consortium, implied warranty, and punitive damages. The M2a-Magnum was part of the "second generation" metal-on-metal total hip arthroplasty ("THA") device group that came to market in the late 1990s-early 2000s. By the early 1970s, the first-generation products were taken off the market due to high failure rates and health concerns for patients. Manufacturers pushed second-generation metal-on-metal THA devices to market without solving the problems with the first-generation products, and, unsurprisingly, patients exhibited the same clinical outcomes. No second-generation THA metal-on-metal devices

remain on the market today. The Court should bar Biomet from introducing any evidence or testimony relating to the issues discussed herein as they are neither relevant nor probative.

LEGAL STANDARD

Under Federal Rule of Evidence 402, only relevant evidence is admissible at trial. Evidence is relevant if it has a tendency to make a fact of consequence to the litigation more or less probable than it would be without the evidence. Fed. R. Evid. 401. However, even relevant evidence can be excluded "if its probative value is substantially outweighed by a danger of one or more of the following: unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403.

The trial court has broad discretion in assessing the probative value of evidence and determining if it is significantly outweighed by the risk of undue prejudice. *Chism v. CNH Am. LLC*, 638 F.3d 637, 641 (8th Cir. 2011). A court should exclude relevant evidence if its probative value is substantially outweighed by a danger of unfair prejudice. Fed. R. Evid. 403.

MOTIONS *IN LIMINE*

P1. Evidence and argument concerning "State of the Art" defense

Plaintiffs ask the Court to order Biomet and its witnesses to refrain from using the term "State of the Art." "State of the Art" is not a viable affirmative defense to any of Plaintiff's pending claims. Mo. Ann. Stat. § 537.764. "State of the Art" evidence had been excluded by Missouri courts when it was not available as an affirmative defense. *Adams v. Fuqua Indus., Inc*., 820 F.2d 271, 274 (8th Cir. 1987); *see Elmore v. Owens–Illinois, Inc.*, 673 S.W.2d 434, 438(Mo. banc 1984)(knowledge is irrelevant for a strict liability design defect claim such that a manufacturer may be liable even though the state of the art was such that the danger was not then scientifically

known). Thus, Defendants should be precluded from using the term to describe their metal-on-metal hip products because it is not a relevant or applicable affirmative defense.

P2. Improper expert opinions

I. Expert Testimony by Any of Plaintiff's Treating Providers Not Disclosed Under F.R.C.P. 26(a)(2)

Federal Rule of Civil Procedure 26(a)(2)(A) requires a party to "disclose to the other parties the identity of any witness it may use at trial to present evidence under Federal Rule of Evidence 702, 703, or 705." For witnesses not specially retained to provide testimony at trial, Rule 26(a)(2)(C) still requires an identification of the subject matter the witness will testify about, a summary of the opinions to be expressed, and the factual basis for such opinions.

Biomet's Expert Disclosures identify nine retained expert witnesses by name. See Exhibit 1, Biomet's Expert Disclosures, pp. 1-4. With respect to Rule 26(a)(2)(C) expert witnesses, Biomet designated "any and all of the Plaintiff's treating physicians and other health care providers," incorporating by reference *any* health care provider listed in any and all of the medical records in this case, as well as the medical records from any such healthcare provider." Ex. 1, pp. 4-5. Plaintiffs request an Order precluding Biomet from eliciting opinion testimony from any of Plaintiff's health care providers not specially identified as an expert by Biomet.[1]

Biomet's non-retained expert disclosures are insufficient. First, the disclosures do not identify any treating physician witness by name, which is a *sine qua non* of sufficient disclosure. *Vanderberg v. Petco Animal Supplies Stores, Inc.*, 906 F.3d 698, 703 (8th Cir. 2018)(holding that disclosure of medical provider in initial disclosures and production of medical records did not satisfy burden to name non-retained treating providers in expert disclosures); *Trekell v. Target*

[1] Biomet did not disclose Dr. Lewallen as an expert witness or describe with specificity the opinion testimony they wish to elicit from him.

Corp., No. 18-662, 2019 WL 6868963, at *5 (W.D. Mo. Dec. 16, 2019)("[t]he supplemental disclosure of these witnesses does not identify them by name and so violates Rule 26.").

Secondly, Biomet's expert disclosures do not identify the opinions to be expressed or the factual basis for the opinions. Simply pointing to the medical records does not satisfy a parties' burden under Rule 26(a)(2)(C). *Vanderberg*, 906 F.3d at 703 (production of medical records did not constitute a compliant expert disclosure of subject matter); *Post v. Dolgencorp, LLC*, No. 19-171, 2020 WL 3412238, at *6 (E.D. Mo. June 22, 2020) (failure to include summary of the facts and opinions to be expressed rendered expert disclosure of treating physicians inadequate).

Witnesses and opinions not properly disclosed under Rule 26 are presumptively excluded from trial as a sanction under Rule 37(c)(1). *Vanderberg*, 906 F.3d at 704. Exclusion is mandated unless the proponent of the testimony can demonstrate that the failure to disclose was substantially justified or harmless. *Id*. Biomet's failure to identify the names of Plaintiff's treating providers it might call as experts at trial is not substantially justified, since by Biomet's own admission, it knew the identify of such potential experts through their review of Plaintiff's medical records. Ex. 1, p. 4. Furthermore, Biomet's failure to disclose the identity of Plaintiff's treating providers, or their opinions, is not harmless. As discussed by the Eighth Circuit in *Vanderberg*, "[l]itigants should not have to guess who will offer expert testimony; they need knowledge to conduct their own discovery and proffer responsive experts." 906 F.3d 698 at 704 (quoting *Cripe v. Henkel Corp.*, 858 F.3d 1110, 1112 (7th Cir. 2017)). Biomet's last-minute attempt to elicit expert testimony at trial from Dr. Lewallen – who consulted with Plaintiff one time and provided no treatment – is exactly the type of trial by ambush tactic meant to be prevented by the disclosure requirements in Rule 26.

II. Testimony or Argument Concerning Alternative Causes of Plaintiff's Injuries Not Supported by Expert Testimony

Just as Plaintiff must present competent expert testimony demonstrating that Biomet's defective product caused her injuries and damages, Biomet must present competent expert testimony supporting any alleged alternate causes of her injuries. Plaintiff seeks an order *in limine* precluding Biomet from eliciting testimony or counsel arguing to the jury concerning alternate causes of Plaintiff's injuries not supported by expert testimony, including the following:

(a) That any of Plaintiff's surgeons breached a standard of care by installing her implant in the wrong position or at an incorrect angle, or otherwise disregarded any instructions related to placement of the implant, whether with respect to her initial implant placement, or any revision implant surgeries[2]

(b) That Plaintiff's subsequent revision-replacement hip implants emit particles causing metallosis, toxicity, or otherwise contribute to her on-going symptoms.

(c) That any fall by Plaintiff contributed to the failure of Biomet's product or contributed to her damages.[3]

(d) That any non-hip-related medical conditions, procedures (including her 2010 back surgery and hardware used in it), medications, or hereditary medical conditions contributed to the failure of her implants or subsequent dislocations.

Biomet's disclosed expert reports have not identified any of these listed factors as specific, alternative causes of Plaintiff's injuries or damages. In some instances, Biomet's experts have pontificated during depositions concerning "general" alternative causes for hip implant failure, but

[2] For example, Defendants' orthopedics expert Dr. Fleeter was directly asked this in his deposition and does not opine that Dr. Martin was negligent or fell below the standard of care. See Exhibit 2, Fleeter Deposition Excerpt, 126:20-127:04; 189:19-190:02.

[3] While evidence of any accidental subsequent falls may be relevant to Plaintiff's damages, there is no expert testimony establishing that any fall contributed to or caused the toxic reaction or failure of Biomet's product, nor is there any evidence that any of Plaintiff's falls were deliberate or intentional

none have expressed "specific" alternative cause opinions. Federal Rules of Evidence 402 and 403 preclude testimony and argument concerning alternative "general" causation, as such testimony or argument is not probative without expert testimony establishing specific alternative causation, and permitting such testimony or argument would invite the jury to decide the issues based on speculation or other improper basis. *See Junk v. Terminix Int'l Co.*, 628 F.3d 439 (8th Cir. 2010)

P3. Evidence and argument concerning Ms. Bayes' conduct post-surgery and evidence regarding placement of Plaintiff's cup by Dr. Martin

Plaintiff anticipates that Biomet will attempt to elicit testimony, make reference to, and/or argue that Plaintiff failed to comply with certain hip precautions after the implantation of the M2a-Magnum device. There is simply no evidence that Plaintiff's abductor muscle was killed/destroyed by any of her post-surgery conduct; so any testimony regarding Plaintiff's conduct post-surgery is irrelevant to the question of fault and liability. "Missouri courts consistently have held that a plaintiff's fault (except an informed assumption of risk or misuse of product) is not relevant in products liability cases…." *LaHue v. Gen. Motors Corp.*, 716 F. Supp. 407, 416 (W.D. Mo. 1989) (citation omitted). In this case, the general rule applies; that is, Plaintiff's fault is simply not relevant in this defective product case. The dislocation of her hip as a result of such ordinary tasks as taking off a sandal or leaning forward to grab a document can in no way be characterized as evidence that Plaintiff made an "informed assumption of the risk," or that she "misused" the M2a-Magnum. Additionally, Mrs. Bayes never had a dislocation while she had a Magnum hip implanted. As such, this Court should prohibit Biomet from improperly suggesting to the jury that Plaintiff's actions contributed to making the M2a-Magnum defective or causing her initial injuries.

Plaintiff further anticipates Biomet will attempt to argue Plaintiff's injuries were a result of the placement of the hip implant by Dr. Martin. Expert testimony is required to support any

allegation that a physician breached or deviated from the applicable standard of care. *Blevens v. Holcomb*, 469 F.3d 692, 693-6 (8th Cir. 2006); *Smith v. Tenet Healthsystem SL, Inc.*, 436 F.3d 879, 886 (8th Cir. 2006). Without evidence that that Dr. Martin's implantation of the Plaintiff's M2a-Magnum fell below the standard of care, there is no proper basis for the jury to conclude his conduct caused or contributed to Plaintiff's injuries.[4] As such, any argument regarding the placement, specifically the alleged vertical position of the implant, should be barred.[5] And Dr. Martin is not a party to this case (so he cannot be apportioned any fault on the verdict form by the jury).[6]

In the event the Court allows testimony about the alleged fault of Dr. Martin stemming from his placement of the hip (and denies Plaintiffs' Daubert motion), such evidence and argument should be limited to Dr. Martin being the *sole* cause of Mrs. Bayes's injuries, not *a* cause or a *contributing* cause.[7] In other words, Biomet should be only able to argue that Dr. Martin is the only one to blame for her injuries, cutting off Biomet's liability; Biomet should not be able to back door a defense laying partial fault on Dr. Martin (as a non-party).

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[4] Dr. Fleeter, one of Defendants' experts, was given every opportunity to say Dr. Martin fell below the standard of care in treating Mrs. Bayes but refused to. See Exhibit 2.

[5] Plaintiffs have an outstanding Daubert challenge to Dr. Fleeter's opinions about the angle of placement based off of X-rays taken months/years after the implant. R. Doc. 113. Should the Court grant that motion, Biomet has no expert evidence that the hip was placed improperly.

[6] *See Kansas City Power & Light Co. v. Bibb & Assoc., Inc.,* 197 S.W.3d 147, 159 (Mo. App. 2006) ("In Missouri, fault is only to be apportioned amount those at trial."). Biomet could have, but did not, make Dr. Martin a party to this case, in which scenario it would be allowed to attempt to apportion some fault to him. Biomet should not be allowed to "back door" evidence of his fault in an attempt to have the jury indirectly apportion some blame to him when they cannot do so directly.

[7] *See Beverly v. Hudak,* 545 S.W.3d 864, 876 (Mo.App. 2018) ("Thus, a defendant may argue that a third party, including a non-party, was the ***sole*** cause of the plaintiff's injuries.") (citation omitted; emphasis in original).

P4. Evidence regarding Plaintiff's Facebook message purporting to blame Dr. Martin

Plaintiff anticipates that Biomet will attempt to elicit testimony, make reference to, and/or argue that Plaintiff blamed Daniel J. Martin, Jr., M.D. – one of her surgeons – for her injuries.[8] This is not relevant and, further, would be vastly more prejudicial to Plaintiffs than probative.

Under Missouri law, Plaintiff is not an expert and is not qualified to offer an opinion about the cause of her injuries. Proof of causation requires expert medical testimony when "the injury is a 'sophisticated' one, i.e., requiring surgical intervention or other highly scientific technique for diagnosis. *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1210 (8th Cir. 2000). Furthermore, under Missouri law, strict liability focuses on the product. *See Pro Serv. Auto., L.L.C. v. Lenan Corp.*, 04-587, 2005 WL 3371054, at *13 (W.D. Mo. Dec. 12, 2005), *aff'd*, 469 F.3d 1210 (8th Cir. 2006); *Spuhl v. Shiley, Inc.*, 795 S.W.2d 573, 577 (Mo. App. 1990). To establish liability in a strict liability design defect case, the plaintiff bears the burden of proving "that the product, *as designed*, is unreasonably dangerous and therefore defective." *Bachtel v. TASER Int'l, Inc.*, 747 F.3d 965, 973 (8th Cir.2014) (citation omitted). The primary inquiry in a design defect case is "whether the product—because of the way it is designed—creates an unreasonable risk of danger" to the consumer or user when put to normal use." *Smith v. Toyota Motor Corp.*, 964 F.3d 725, 729 (8th Cir. 2020) (citation omitted). As this is a design defect products liability case, whether Ms. Bayes may have blamed Dr. Martin for not being a "fellowship trained total joint orthopedic" doctor is simply not relevant. Moreover, such a suggestion would be vastly more prejudicial than probative as it could cause the jury to improperly focus on matters outside of whether the M2a-Magnum was defective. Looking at the message itself, Mrs. Bayes ruled out the M2a Magnum as being defective because it had not been recalled at the time she wrote the message. The only

[8] This expectation is based on a Facebook message posted by Ms. Bayes on April 10, 2011. See Exhibit 3.

remaining party left to blame, then, was Dr. Martin. This is not a scientific methodology and is irrelevant on a question that experts opine on. The message should therefore be excluded as both irrelevant (because of its insufficiency) and unduly prejudicial.

P5. Evidence and argument about the failure to preserve the Biomet M2a-Magnum hip post-revision

Under Missouri law, Plaintiff can prove the elements of her design defect claim by use of circumstantial evidence rather than direct evidence; the defective product itself is not essential to such proof. *See Pritchett v. Cottrell, Inc.*, 512 F.3d 1057, 1064 (8th Cir. 2008); *Brissette v. Milner Chevrolet Co.*, 479 S.W.2d 176, 181-82 (Mo. Ct. App. 1972). Even if this type of evidence were relevant, which Plaintiff firmly disputes, revealing to the jury that the device was not preserved would be vastly more prejudicial than probative.

In response to Plaintiffs' Motion for Summary Judgment, R. Doc. 118, Defendants put forth their best evidence to show that Mrs. Bayes intentionally destroyed her hip to keep the evidence from Biomet. R. Doc. 145. Yet they fell short of showing any evidence that she acted intentionally. For example, there is no proof that she told or instructed her surgeon before, during, or after surgery to dispose of the left hip in 2011, two years before she filed suit.[9] And there are no facts similar to that which could can be construed to evidence Mrs. Bayes had any intent to hide the truth. As outlined in Plaintiffs' original Memorandum in Support, the explanted left hip would have been hazardous waste with special requirements for its disposal. When what later becomes

[9] Defendants have alluded to the fact that her surgeon, Dr. Lux, eventually became a retained expert after she filed suit. At the time of the surgery, however, Mrs. Bayes had not hired a lawyer. So Dr. Lux could not have been an expert at that time and was nothing more than a treating physician.

evidence is disposed of in accordance with normal standing procedures before suit, intent and bad faith are lacking, and adverse inference instructions are inappropriate.[10]

Defendants have not made a *prima facie* showing of bad faith or intent, so they are not entitled to spoliation-related relief. Assuming *arguendo,* that what Biomet points to as evidence supporting spoliation is true, at best it *may* amount to some sort of *negligent* spoliation (which Plaintiffs do not believe to be the case). But that is not enough for any sort of sanction or adverse inference instruction. The unknown whereabouts of Mrs. Bayes left hip are therefore irrelevant to any of the claims or defenses in this case. Thus, under Fed. R. Evid. 401 and 402, facts, testimony and/or argument about its unknown location should be excluded from the trial as irrelevant.

Furthermore, even if it were somehow relevant, putting on a mini-trial related to whether Mrs. Bayes should have instructed her surgeon to keep her left hip would be overly prejudicial due to the implication that Mrs. Bayes in some way did something wrong, especially since Defendants cannot show she destroyed the left hip intentionally.

The Court must, at some point, make a determination as to whether Mrs. Bayes acted intentionally. *See Hallmark Cards,* 703 F.3d at 460 ("a district court is required to make two findings before an adverse inference instruction is warranted…."). Given that Biomet has put forth its best evidence in opposing Plaintiffs' summary judgment motion, the Court should make that determination before trial. Because when discussion, argument, and/or evidence of spoliation is

[10] *See Morris v. Union Pacific R.R.,* 373 F.3d 896 (8th Cir. 2004) (rejecting a "known or should have known" standard; requiring an intentional destruction by a party; and finding that an adverse inference instruction was unwarranted even after a train crash with injuries where the alleged evidence was disposed of in the ordinary course of business); *cf. Stevenson v. Union Pacific R.R. Co.,* 354 F.3d 739 (8th Cir. 2004) (finding the minimum limits for intentional destruction where a party was a serial litigant, knew tapes would be relevant, normally kept them when the evidence on them was helpful, immediately knew of a potential claim right after the incident occurred, and sought to preserve all evidence except the tape).

presented at a trial but is not warranted, the issue of spoliation "creates a substantial danger of unfair prejudice." *Morris,* 373 F.3d at 903; *see also Hallmark Cards,* 703 F.3d at 461 (discussing the gravity of spoliation and the branding of one party as a bad actor). Additionally, facts, testimony and argument related to the current unknown whereabouts of Mrs. Bayes's left hip explant should therefore alternatively be excluded under Fed.R.Evid. 403 as unfairly prejudicial, because Biomet cannot show that Mrs. Bayes acted intentionally with evil intent to destroy evidence.

P6. Evidence and argument related to allegations of malpractice without a determination of fault.

Plaintiff anticipates that Biomet will attempt to elicit testimony, make reference to, and/or present argument with respect to the fact that some of the physicians testifying in the matter have been the subject of a malpractice action. However, none of the physicians Plaintiff anticipates calling have had a determination or adjudication that they committed malpractice by a court or a licensing board. Moreover, none of the allegations against the physicians dealt with truthfulness or lack thereof that would be implicated under Fed. Rule of Evidence 608. Thus, this evidence should be should be precluded under Fed. Rules of Evidence 403 and 404.

The Eighth Circuit has "interpreted Rule 404(b) as permitting evidence of prior acts if it is '(1) relevant to a material issue; (2) proved by a preponderance of the evidence; (3) higher in probative value than in prejudicial effect; and (4) similar in kind and close in time to the event at issue.'" *Batiste– Bair v. Callahan*, 664 F.3d 1225, 1228–29 (8th Cir. 2012) (citing *Davis v. Lincare, Inc.,* 526 F.3d 377, 380 (8th Cir. 2008)). Allegations of malpractice against these physicians have not been proven by a preponderance of the evidence in a court or by a licensing board, and Defendants have no experts that speak to these issues. Allowing evidence of

malpractice without an ultimate determination of fault on behalf of the doctor will result in substantial prejudice, with essentially no probative value.

P7. Evidence and argument concerning Biomet's good corporate deeds or philanthropy

Plaintiff anticipates that Biomet may attempt to argue or suggest to the jury during trial that they are "good" companies that benefit society by making medical devices that improve people's lives, making charitable contributions or engaging in other good acts. The only conceivable purpose for such evidence would be to purport that Biomet is a "good company" and thus unlikely to make harmful products or irresponsible decisions. Even assuming this type of evidence is relevant and not otherwise barred as unfairly prejudicial by Rule 403 – which is unlikely – this is precisely the sort of propensity evidence that Rule 404(a)(1) is meant to bar.[11]

P8. Evidence and argument concerning healthcare costs and insurance as collateral source

Plaintiff respectfully requests that the Court instruct Biomet and its counsel not to comment on, refer to, or introduce testimony or evidence relating to the fact that Plaintiffs are only entitled to reimbursement for the amounts paid for the medical expenses by a third-party insurer. *See Brancati v. Bi-state Dev. Agency*, 2018 WL 6613412 (Mo. App. 2018) (finding the trial court did not err and there was no prejudice in admitting evidence of the "amount charged" for medical bills because the "amount charged" could be admitted under either the former or the amended version of MO Rev. Stat. 490.715.5). In 2017, Missouri passed SB31 in derogation of the common law collateral source rule; however, the bill was silent on the issue of retroactivity. If there is any

[11] *See, e.g., Radiance Capital Receivables Eighteen, LLC v. Concannon,* 16-04280, 2017 WL 4533449, at *5 (W.D. Mo. Oct. 10, 2017), *aff'd*, 920 F.3d 552 (8th Cir. 2019*)*; *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Practices & PMF Products Liab. Litig.*, 09-10012, 2011 WL 6740391, at *19 (S.D. Ill. Dec. 22, 2011); *Niver v. Travelers Indem. Co. of Illinois*, 433 F.Supp.2d 968, 995 (N.D. Iowa 2006) (granting motion in limine to preclude evidence of "good acts" as irrelevant even for purposes of punitive damages claim).

question as to its retroactive application, the balance should be struck in favor of retaining the common law remedy. *See Overcast v. Billings Mutual Ins. Co.*, 11 S.W.3d 62, 69 (Mo. banc 2000). Therefore, the new law should be construed not to impact Plaintiffs' common law remedy as it existed prior to the 2017 amendment. Plaintiffs here filed their suit in 2013, years before Missouri changed its rule in 2017. *See* MO Rev. Stat. 490.715 (2017). Thus, Plaintiff requests that the Court exclude any argument that Plaintiffs are only due reimbursement for past medical expenses at their paid rate (vs. their billed rate).

P9. References to litigation crisis or the effect of any verdict on future medical costs

Given the highly charged political climate we are currently facing, Plaintiff requests that Biomet and its witnesses be ordered to refrain from offering evidence, statements, opinions, making argument about, or otherwise making any comments or suggestions regarding a tort reform crisis, the need for tort reform, medical drug and device costs or the effect of this trial on businesses, health insurance or medical costs in general. Plaintiff has a right to utilize our civil justice system, which allows for her to be compensated monetarily, and the structure of our legal system should not be used to impugn Ms. Bayes. These comments and suggestions are improper, insert factors that are not relevant, are highly prejudicial, add no probative value and are only meant to appeal to the jury's sympathy. Thus, under Fed. Rules of Evidence 401, 402, and 403, such evidence should be prohibited.

P10. Effect of FDA clearance

Plaintiff respectfully requests that this Court preclude counsel for Biomet and all of its witnesses from commenting on, referring to, attempting to introduce testimony or evidence, or arguing or insinuating that the FDA clearance of the M2a-Magnum indicates that the FDA believed

the benefits of the device outweighed the risks (meaning that it was safe for use).[12] Put differently, because FDA clearance does not absolve Biomet from liability (or else there would have been a preemption argument), Biomet should not be able to suggest that the FDA found the device to be safe or approved its design. Such argument is not only improper and would allow Biomet to use the FDA as an out of court expert that cannot be cross-examined by Plaintiffs. And it misstates what the FDA clearance indicates. *See In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Products Liab. Litig.*, 401 F.Supp.3d 538, 549 (D. Md. 2019), *motion to certify appeal denied sub nom*., 2019 WL 6345746 (noting that a § 510(k) review takes an average of 20 hours, does not require an independent review of a device's safety and efficacy).[13] In addition, Biomet should be barred from introducing any evidence or testimony that Biomet actually complied with FDA clearance regulations because Biomet has not identified a regulatory expert who opines that Biomet actually met every requirement of the FDA clearance process and its ongoing obligations under FDA regulations.

Plaintiff further requests that the Court instruct the jury that regulations of the FDA are minimal in nature and that compliance with such regulations does not immunize a manufacturer from liability caused by its products. Plaintiff anticipates that Biomet will repeatedly rely upon the argument that Biomet allegedly complied with FDA regulations in the manufacture and sale of the M2a-Magnum, and that the FDA never forced the product off the market. But neither of those facts determines whether, under Missouri law, the M2a Magnum is unreasonably, because the

[12] Biomet should also be precluded from using the word "approval" or "FDA-approved" when describing the M2a Magnum as it undisputedly did not use the Premarket Approval Process, which actually results in FDA approval.

[13] *See also, In re DePuy Orthopaedics Inc. Pinnacle Hip Products Liab. Litig.,* 3:11-MD-2244-K, 2014 WL 3557392, *1 (N.D. Tex. July 18, 2004) ("[t]he FDA never passed on the original design of the device and imposed no requirements for safety or otherwise on it. The FDA merely determined whether the Pinnacle Device was substantially equivalent to a grandfathered device.").

FDA never evaluated the device's safety and efficacy before clearing it onto the market. In sum, Biomet cannot insinuate that FDA clearance absolves it from liability, and the jury should be properly instructed on that difficult point of interaction between state and federal law.

P11. Evidence and argument about adequacy of label and Dr. Martin's reading of the Instructions for Use

Biomet filed a motion for summary judgment on Plaintiff's failure to warn claims. Rec. Doc. 124. The Court granted this motion on the basis of causation, pretermitting any decision as to the adequacy of the warning. Rec. Doc. 225. The adequacy of the warnings has no relevance to Plaintiff's existing remaining claims, so evidence relating to the adequacy of the warnings in the Instructions for Use should be excluded. *See C.C. through Ginnever v. Suzuki Mfg. of Am. Corp.*, 16-1271, 2018 WL 4504687, at *6 (E.D. Mo. Sept. 20, 2018). Under Plaintiffs' design defect claims, Biomet is liable if Plaintiff proves the design of the M2a-Magnum created an unreasonable risk of danger which damaged Plaintiff. Thus, any argument or testimony regarding the adequacy of the warnings should be prohibited.

Additionally, the Court should preclude mention of whether Dr. Martin read the Instructions for Use. That Dr. Martin testified that he did not read them resulted in the dismissal of Plaintiffs' failure to warn claims. Whether Dr. Martin read the Instructions for Use is irrelevant to the remaining issues surrounding Plaintiffs' design defect claims and would be overly prejudicial to Plaintiffs. Dr. Martin is not a party to the case and under Missouri law can have no fault apportioned to him. Additionally, no Biomet expert opines that Dr. Martin fell below the standard of care by not reading the Instructions for Use. Eliciting this testimony would be nothing more than a Biomet "back door" attempt to have the jury apportion some fault to him when they cannot do so directly.[14]

[14] The Instructions for Use do not provide any instruction to doctors on the proper placement angle.

Dated: September 8, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 8, 2020, a copy of the above and foregoing was filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the all counsel of record registered to receive electronic Notices of Electronic Filing generated by CM/ECF.

/s/ Allison Brown
Allison Brown, paralegal